Complete Summary

GUIDELINE TITLE

Dry eye syndrome.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Dry eye syndrome. San Francisco (CA): American Academy of Ophthalmology (AAO); 2008. 28 p. [99 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Dry eye syndrome. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 21 p.

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COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Dry eye syndrome

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Ophthalmology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To preserve and/or improve vision, prevent or minimize structural damage to the ocular surface, and improve patient comfort, by addressing the following goals:

- Establish the diagnosis of dry eye, differentiating it from other causes of irritation and redness
- Identify the causes of dry eye
- Establish appropriate therapy
- Relieve discomfort
- Prevent complications, such as loss of visual function, infection, and structural damage
- Educate and involve the patient in the management of this disease

TARGET POPULATION

Individuals of all ages who present with symptoms and signs suggestive of dry eye, such as irritation, redness, fluctuating vision, and decreased tear meniscus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Medical and ocular history
2. Physical examination
    - Visual acuity
    - External examination
    - Slit-lamp biomicroscopy
3. Diagnostic tests
    - Assessment of corneal sensation, when indicated
    - Laboratory and clinical evaluation for autoimmune disorders, when indicated

Management/Treatment

1. Education and environmental modifications
2. Elimination of offending topical or systemic medications where feasible

3. Topical medication (e.g., artificial tear substitutes, gels/ointments; cyclosporine and corticosteroids; mucolytic agents; autologous serum tears)
4. Systemic medication (e.g. omega-3 fatty acids, tetracyclines, cholinergic agonists, anti-inflammatory agents)
5. Surgical treatment (e.g., punctal plugs, permanent punctual occlusion, tarsorrhaphy, correction of eyelid abnormalities)
6. Other treatment (e.g., warm compresses and eyelid hygiene, and contact lenses)
7. Follow-up
8. Counseling and referral

MAJOR OUTCOMES CONSIDERED

- Effectiveness of therapies
    - Reduction or alleviation of signs and symptoms
    - Maintenance and improvement visual function
    - Reduction or prevention of structural damage
- Adverse effects of therapies

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In the process of revising this document, a detailed literature search of articles in the English language was conducted in December 2007 in PubMed and the Cochrane Library on the subject of dry eye for the years 2002 to 2007.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Ratings of Strength of Evidence

Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.

Level II includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] panel consensus with external peer review)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of dry eye were reviewed by the Cornea/External Disease Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient's care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of importance to care process

Level A, defined as most important
Level B, defined as moderately important
Level C, defined as relevant but not critical

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 2008).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The ratings of importance to the care process (A-C) and the ratings of strength of evidence (I-III) are defined at the end of the "Major Recommendations" field.

Diagnosis

The initial evaluation of a patient who presents with symptoms suggestive of dry eye should include those features of the comprehensive adult medical eye evaluation relevant to dry eye (American Academy of Ophthalmology Preferred Practice Patterns Committee, 2005). [A:III]

Patient History

- Symptoms and signs [A:III]
- Exacerbating conditions [B:III]
- Duration of symptoms [A:III]
- Topical medications used, their frequency, and their effect on symptoms [A:III]
- Contact lens wear, schedule, and care [A:III]
- Allergic conjunctivitis [B:III]
- Ocular surgical history [A:III]
- Ocular surface disease [A:III]
- Punctal surgery [A:III]
- Eyelid surgery [A:III]
- Bell palsy [A:III]
- Smoking or exposure to second-hand smoke [A:III]
- Dermatological diseases [A:III]
- Technique and frequency of facial washing including eyelid and eyelash hygiene [A:III]
- Atopy [A:III]
- Menopause [A:III]
- Systemic inflammatory diseases [A:III]
- Other systemic conditions [A:III]
- Systemic medications [A:III]
- Trauma [B:III]
- Chronic viral infections [B:III]
- Nonocular surgery [B:III]
- Radiation of orbit [B:III]
- Neurological conditions [B:III]
- Dry mouth, dental cavities, oral ulcers [B:III]

Examination

The physical examination includes a visual acuity measurement, [A:III] an external examination, [A:III] and slit-lamp biomicroscopy. [A:III]

The external examination should pay particular attention to the following:

- Skin [A:III]
- Eyelids [A:III]
- Adnexa [A:III]
- Proptosis [B:III]
- Cranial nerve function [A:III]
- Hands [B:III]

The slit-lamp biomicroscopy should focus on the following:

- Tear film [A:III]
- Eyelashes [A:III]
- Anterior and posterior eyelid margins [A:III]
- Puncta [A:III]
- Conjunctiva
    - Inferior fornix and tarsal conjunctiva [A:III]
    - Bulbar conjunctiva [A:III]
- Cornea [A:III]

Diagnostic Tests

Corneal sensation should be assessed when trigeminal nerve dysfunction is suspected (Heigle & Pflugfelder, 1996). [A:III] A laboratory and clinical evaluation for autoimmune disorders should be considered for patients with significant dry eyes, other signs and symptoms of an autoimmune disorder (e.g., dry mouth), or a family history of an autoimmune disorder. [A:III]

Treatment

Specific treatment recommendations depend on the severity and source of the dry eye. The sequence and combination of therapies should be determined on the basis of the patient's needs and preferences and the treating ophthalmologist's medical judgment. [A:III] The table below lists treatments for dry eye syndrome based on the severity level of the disease. Specific therapies may be chosen from any category regardless of the level of disease severity, depending on physician experience and patient preference.

Treatment Recommendations for Dry Eye Syndrome by Disease Severity Level*

Mild	• Education and environmental modifications [A:III] • Elimination of offending topical or systemic medications [A:III] • Aqueous enhancement using artificial tear substitutes, gels/ointments [A:III]

	• Eyelid therapy (warm compresses and eyelid hygiene) [A:III] • Treatment of contributing ocular factors such as blepharitis or meibomianitis [A:III] (see the National Guideline Clearinghouse (NGC) summary of the American Academy of Ophthalmology (AAO) guideline Blepharitis)
Moderate	*In addition to above treatments*: • Anti-inflammatory agents (topical cyclosporine [U.S. Food and Drug Administration, 2003; Sall et al., 2000] [A:I] and corticosteroids [Pflugfelder et al., 2004; Marsh & Pflugfelder, 1999; Prabhasawat & Tseng, 1998; Sainz De La Maza Serra, Simon Castellvi, & Kabbani, 2000], [A:II] systemic omega-3 fatty acids supplements [Creuzot et al., 2006; Miljanovic et al., 2005]) [A:II] • Punctal plugs [A:III] • Spectacle side shields and moisture chambers [A:III]
Severe	*In addition to above treatments*: • Systemic cholinergic agonists (Vivino et al., 1999; Petrone et al., 2002; Nelson et al., 1998) [A:I] • Systemic anti-inflammatory agents [A:III] • Mucolytic agents [A:III] • Autologous serum tears (Tsubota et al., 1999; Chiang et al., 2007) [A:III] • Contact lenses [A:III] • Correction of eyelid abnormalities [A:III] • Permanent punctal occlusion [A:III] • Tarsorrhaphy [A:III]

*Adapted with permission from Pflugfelder SC (Chair). Management and therapy Subcommittee of the International Dry Eye Workshop. Management and therapy of dry eye disease: report of the management and therapy Subcommittee of the International Dry Eye Workshop (2007). Occul Surf 2007;5:174.

Follow-Up

The frequency and extent of the follow-up evaluation will depend on the severity of disease, the therapeutic approach, and response to the therapy. For example, patients with sterile corneal ulceration associated with dry eye may require daily follow-up. [A:III]

Provider and Setting

Patients with dry eye who are evaluated by non-ophthalmologist health care providers should be referred promptly to the ophthalmologist if any of the following occurs: [A:III]

- Visual loss
- Moderate or severe pain
- Lack of response to the therapy
- Corneal infiltration or ulceration

Counseling/Referral

The most important aspects of caring for patients with dry eye are to educate them about the chronic nature of the disease process and to provide specific instructions for therapeutic regimens. It is helpful to reassess periodically the patient's compliance and understanding of the disease, the risks for associated structural changes, and to re-inform the patient as necessary. [A:III] The patient and physician together can establish realistic expectations for effective management.

Patients with pre-existing dry eye should be cautioned that refractive surgery may worsen their dry eye condition. [A:III] Patients who have dry eye and are considering refractive surgery should have the dry eye treated before surgery (American Academy of Ophthalmology Basic and Clinical Science Course Subcommittee, 2008).

Definitions:

Ratings of Importance to Care Process

Level A, defined as most important
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Ratings of Strength of Evidence

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for most recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate and timely diagnosis and appropriate treatment and management will preserve and/or improve vision, prevent or minimize structural damage to the ocular surface, and improve patient comfort.

POTENTIAL HARMS

- While *topical cyclosporine 0.05%* is typically well tolerated, ocular burning was reported in 17% of the patients in one study.
- Patients prescribed *corticosteroids* for dry eye should be monitored for adverse effects such as increased intraocular pressure, corneal melting, and cataract formation.
- The most common side effect from taking *cholinergic agonist pilocarpine* was excessive sweating that occurred in over 40% of patients. Two percent of the patients taking oral pilocarpine withdrew from the study because of this and other drug-related side effects.
- *Soft contact lenses* are effective in preventing recurrence of filamentary keratopathy but are poorly tolerated if the patient has severe dry eyes. If the patient has associated neurotrophic keratopathy, contact lenses should be avoided.
- *Punctal plugs* that are displaced into the lacrimal system may pass through the entire system, but blockage with secondary infection has been reported. Rarely, surgical removal is necessary. *Intracanalicular plugs* may offer ease of insertion and a decreased chance of extrusion, but they have been associated with the occurrence of epiphora, canaliculitis, and dacryocystitis.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- **Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual**. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these Preferred Practice Patterns will

not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients' needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.

- **Preferred Practice Pattern guidelines are not medical standards to be adhered to in all individual situations**. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.
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IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Sep (revised 2008 Sep)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology without commercial support

GUIDELINE COMMITTEE

Cornea/External Disease Panel; Preferred Practice Patterns Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Cornea/External Disease Panel: Christopher J. Rapuano, MD, *Chair*; Robert S. Feder, MD; Matthew R. Jones, MD; Francis S. Mah, MD; Ayman Naseri, MD; Audrey R. Talley-Rostov, MD; Andrew J. Velazquez, MD; Jayne S. Weiss, MD; David C. Musch, PhD, MPH, Methodologist

Members of the Preferred Practice Patterns Committee: Sid Mandelbaum, MD, *Chair*; Emily Y. Chew, MD; Linda M. Christmann, MD; Douglas E. Gaasterland, MD; Stephen D. McLeod, MD; Samuel Masket, MD; Christopher J. Rapuano, MD; Donald S. Fong, MD, MPH, Methodologist

Academy Staff: Flora C. Lum, MD; Nancy Collins, RN, MPH; Doris Mizuiri

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

These panel and committee members have disclosed the following financial relationships occurring from January 2007 to October 2008:

Robert S. Feder, MD: Alcon Laboratories, Inc. – Lecture fees

Donald S. Fong, MD, MPH: Merck – Consultant/Advisor

Douglas E. Gaasterland, MD: Inspire Pharmaceuticals – Consultant/Advisor; IRIDEX – Consultant/Advisor, Equity owner, Patents/Royalty

Francis S. Mah, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Lecture fees, Grant support; Allergan, Inc. – Consultant/Advisor, Lecture fees, Grant support; BD Medical - Ophthalmic Systems – Lecture fees; InSite Vision, Inc. – Consultant/Advisor, Lecture fees, Grant support; Inspire Pharmaceuticals, Inc. – Consultant/Advisor, Lecture fees, Grant support; Ista Pharmaceuticals – Consultant/Advisor, Lecture fees, Grant support; Mpex, Inc. – Consultant/Advisor, Grant support; Polymedix, Inc. – Consultant/Advisor, Grant support; Xoma, Inc. – Consultant/Advisor, Grant support

Samuel Masket, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Lecture fees, Grant support; Allergan, Inc. – Lecture fees; Bausch & Lomb, Inc. – Lecture fees; Omeros Pharmaceuticals, Inc. – Consultant/Advisor; Othera Pharmaceuticals, Inc. – Consultant/Advisor; PowerVision – Consultant/Advisor; Visiogen, Inc. – Consultant/Advisor

Stephen D. McLeod, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Grant support; InSite Vision, Inc. – Consultant/Advisor, Visiogen, Inc. – Consultant/Advisor, Equity owner, Grant support

David C. Musch, PhD, MPH: Acuity Pharmaceuticals – Consultant/Advisor; AqueSys, Inc. – Consultant/Advisor; Bausch & Lomb, Inc. – Consultant/Advisor; Glaukos Corp. – Consultant/Advisor; IRIDEX – Consultant/Advisor; MacuSight, Inc. – Consultant/Advisor; Midwest EyeBanks – Grant support; National Eye Institute – Grant support; NeoVista, Inc. – Consultant/Advisor; Neurotech USA, Inc. – Consultant/Advisor; OPKO Health, Inc. – Consultant/Advisor; XTL Biopharmaceuticals – Consultant/Advisor

Ayman Naseri, MD: QLT Phototherapeutics, Inc. – Equity owner; SurModics, Inc. – Equity owner

Christopher J. Rapuano, MD: Alcon Laboratories, Inc. – Lecture fees; Allergan, Inc. – Consultant/Advisor, Lecture fees; Inspire Pharmaceuticals – Lecture fees; Ista Pharmaceuticals – Lecture fees; Rapid Pathogen Screening – Equity/owner; Ziemer Ophthalmic Systems AG – Consultant/Advisor

Audrey R. Talley-Rostov, MD: Addition Technology – Consultant/Advisor, Lecture fees; Advanced Medical Optics – Consultant/Advisor, Lecture fees; Allergan, Inc. – Consultant/Advisor, Lecture fees; Visiogen, Inc. – Consultant/Advisor

Jayne S. Weiss, MD: Alcon Laboratories, Inc. – Lecture fees

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Summary benchmarks for preferred practice patterns. San Francisco (CA): American Academy of Ophthalmology; 2008 Nov. 22 p.

Electronic copies: Available in Portable Document Format (PDF) or Personal Digital Assistant (PDA) format from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 20, 1999. The information was verified by the guideline developer on April 23, 1999. This summary was updated by ECRI on April 9, 2004. The information was verified by the guideline developer on May 20, 2004. This NGC summary was updated by ECRI Institute on April 22, 2009. The updated information was verified by the guideline developer on May 15, 2009.

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